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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,013	04/26/2000	Toshiro Ono	L0461/7086(JRV)	1882

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
01/08/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 09/559,013	Applicant(s) ONO ET AL.	
	Examiner Karen A. Canella	Art Unit 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 54,56,60,62,64,66,76,133 and 137 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 54,60,62,64 and 66 is/are allowed.
- 6) ☐ Claim(s) 56,76 and 133 is/are rejected.
- 7) ☐ Claim(s) 137 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>Alignments 1-3</u>                    |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2007 has been entered.

Claim 76 has been amended. Claims 54, 56, 60, 62, 64, 66, 76, 133 and 137 are pending and under consideration.

It is restated that The disclosure of the prior-filed application, Application No. 60/168,353, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application does not provide a written description for SEQ ID NO:23. Accordingly the effective priority date will be the filing date of the 09/559013, April 26, 2000.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claim 76 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a kit comprising isolated nucleic acid sequence consisting of SEQ ID NO:27 and SEQ ID NO:28, does not reasonably provide enablement for a kit comprising a pair of isolated nucleic acids which consist essentially of 12-32 contiguous nucleotides of SEQ ID NO:23, nucleic acid molecules which differ from that of (a) due to codon degeneracy, and (c) complements of (a) or (b), wherein the pairs of isolated nucleic acid molecules do not overlap. The specification does not enable any person skilled in the art to which it pertains, or with which

it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The instant claim is drawn to primer pairs. Ashlock et al (Proceedings of the IEE Symposium on Computational Intelligence in Bioinformatics and Computational Biology, 2004, pp. 190-197) that out of a collection of 27408 hypothetical "correct" primer pairs 17224 amplify correctly while 10184 fail to amplify at all or amplify multiple targets (page 191, second column, lines 10-13). Thus, it cannot be expected that all of the primers encompassed by this claim will be useful for the polymerase chain reaction to amplify SEQ ID NO:23 or polynucleotides encoding SEQ ID NO:24 and therefore one of skill in the art would be subjected to undue experimentation in order to use the broadly claimed primer pairs.

Applicant has amended the claim in order to limit the primers pairs to those including primers which hybridize to opposing strands, however, the amendment has failed to overcome the unreliability in art as set forth in the above paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al (WO 98/57976 reference B3 of the IDS filed February 22, 2002).

Claims 56 is drawn to an isolated nucleic acid selected from the group consisting of a fragment of SEQ ID NO:23 of at least 50 nucleotides and full length complements of said fragments, wherein the isolated nucleic acid includes a sequence of contiguous nucleotides which is not identical to SEQ ID NO:33.

It is noted that SEQ ID NO:33 is the reverse compliment of nucleotides 982 to 454 of the instant SEQ ID NO:23 (alignment 1).

Jacobs et al disclose fragments of Sequence Identifier 11, specifically nucleotides 224-679 which correspond to nucleotides 227-686 of the instant SEQ ID NO:23(page 13, lines 3-4 )

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as evidenced by the attached alignment-2. Jacobs et al disclose polynucleotides encoding residues 62-212 of Sequence Identifier 12 (page 13, lines 9-11) which also meets the limitations of the instant claims.

Claims 56 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumas-Milne-Edwards et al (WO99/06549).

Dumas-Milne-Edwards et al disclose Sequence Identifier 60 having a fragment of SEQ ID NO:23 from nucleotide 30 to nucleotide 113, as evidence by the attached alignment-3, thus fulfilling the limitations of both claims 56 and 133.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

Claims 54, 60, 62, 64, 66 are allowed.

Claim 137 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/  
Ph.D., Primary Examiner  
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